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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/696,255

10/29/2003

Kimberly Kline

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7913

20350

7590

05/25/2006

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EXAMINER

YAO, LEI

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/696,255	<b>Applicant(s)</b> KLINE ET AL.	
	<b>Examiner</b> Lei Yao, Ph.D.	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1, drawn to an isolated p53 mutated protein, classified in class 530, subclass 350.
  - II. Claims 2-7, drawn to an isolated nucleic acid, vector, and host cells, classified in class 536, subclass 23.1.
  - III. Claims 8-9, drawn to a method of increasing a cell's sensitivity to an apoptotic inducing agent, comprising the step of administering to said cell a vector, classified in class 514, subclass 44.
  - IV. Claims 10-11, drawn to a method of inhibiting tumor cell growth, comprising the step of administering to said tumor cell a vector to inhibit tumor growth by inducing an effect, classified in class 514, subclass 44.
  - V. Claims 12-22, drawn to a method for the treatment of cell proliferate diseases in an individual, comprising the step of administering to said individual a vector in the form of an aerosolized liposome, and further comprising the step of administering irradiation or an anti-cancer compound, classified in class 514, subclass 1.
  - VI. Claims 23-26, drawn to liposome composition, comprising a vector, carbon dioxide and other material at defined ratio, classified in class 424, subclass 12.1.

**Further restriction:**

If applicants elect any one of the groups set forth above, further **restriction** is required under 35 U.S.C. 121:

- A. Elect SEQ ID NO: 2 or 8

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to *different* products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs is a unique and separately patentable sequence, requiring a unique search of the prior art.

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Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

**In order to be fully responsive, Applicant must elect one from Groups I-VI, and one from Group A if the elected invention group II-VI even though the requirement is traversed. Applicant is advised that neither I - VI nor A is species election requirements; rather, each of I - VI and A is a restriction requirement.**

Inventions are distinct each from the other because of the following reasons:

The polypeptide of group I and polynucleotide of group II are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group II does not necessarily encode a polypeptide of group I. Similarly, the nucleic acid molecule is complementary to the coding sequence, and therefore would not encode the polypeptide of group I. Furthermore, the information provided by the polynucleotide of group II can be used to make a materially different polypeptide than that of group I. In addition, while a polypeptide of group II can be made by methods using some, but not all, of the polynucleotides that fall within the scope of group II, it can also be recovered from a natural source using biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of groups I and II are patentably distinct.

Furthermore, searching the inventions of groups I and II together would impose a serious search burden. The search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. There is

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search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. As such, it would be burdensome to search the inventions of groups I and II together.

Inventions Group II and group III-IV, Group VI and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group I can be used to produce protein as opposed to being used to be administered to a patient for treating a disease related to tumor. Group V can be treated with other reagent comprising the nucleic acid as opposed to being used to be given in the liposome form of invention VI.

Because these inventions are distinct for the reasons given above, each invention has acquired a separate status in the art, and the search required for one group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps. Prior art, which teaches a polypeptide, would not necessarily be applicable to the method of using them. Searching the inventions of Groups together would impose serious search burden. Therefore, restriction for examination purposes as indicated is proper.

#### ***Election of Species***

This application contains claims directed to the following patentably distinct species of the claimed invention:

- a. An tag listed in claim 5 and a host cell listed in claim 7.
- b. An apoptotic inducing agent listed in claim 9.
- c. An inducing effect listed in claim 11.
- d. An Anti-cancer compounds listed in claim 15.

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e. A neoplastic disease listed in claim 18, or a nonneoplastic disease listed in claim 19 or 21, or an autoimmune disease listed in claim 20, or inflammatory process listed in 22.

In the event that applicant elects invention II applicant is required under 35 U.S.C. 121 to elect a single disclosed species from a) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that applicant elects invention III, applicant is required under 35 U.S.C. 121 to elect a single disclosed species from b) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that applicant elects invention IV, applicant is required under 35 U.S.C. 121 to elect a single disclosed species from c) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that applicant elects invention V, applicant is required under 35 U.S.C. 121 to elect a single disclosed species from d) and a single disclosed disease species from e) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of

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inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. 821.04. Process claims that depend from or otherwise include all the limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that process claims should be amended during prosecution either to maintain dependency on the product claims or otherwise include the limitation of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-4.30pm Monday to Friday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LY

Lei Yao, Ph.D.  
Examiner  
Art Unit 1642

  
**JEFFREY SIEW**  
**SUPERVISORY PATENT EXAMINER**